Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

Claim 1. (original): A topical formulation for treating migraines or cluster headaches, muscle sprains, muscle spasms, spasticity, tension headaches, tension related migraines and related conditions associated with muscle tension and pain comprising:

a therapeutically effective amount of an active agent(s) incorporated into a pharmaceutically acceptable excipient for topical administration onto the skin of a human patient, the active agent(s) being selected from the group consisting of:

i) an ergot alkaloid;

ii) a skeletal muscle relaxant; or

iii) a combination of an ergot alkaloid and a skeletal muscle relaxant;

the active agent(s) being present in an effective concentration such that a unit dose of the topical formulation provides a therapeutic effect within about 2 hours after topical administration to the human patient.

Claim 2. (original): The formulation of claim 1, wherein the formulation further comprises a therapeutically effective amount of a serotonin agonist.

Claim 3. (currently amended): The formulation of claims 1 ~~and 2~~, wherein the therapeutically effective amount of active agent is an ergot alkaloid.

Claim 4. (currently amended): The formulation of claims 1 ~~and 2~~, wherein the therapeutically effective amount of active agent is a skeletal muscle relaxant.

Claim 5. (currently amended): The formulation of claims 1 ~~and 2~~, wherein the therapeutically effective amounts of active agents are an ergot alkaloid and a skeletal muscle relaxant.

Claim 6. (original): The formulation of claim 1, wherein the formulation provides relief from a condition selected from the group consisting of migraines, cluster headaches, muscle sprains, muscle spasms, spasticity, tension headaches and tension related migraines.

Claim 7. (original): The formulation of claim 2, wherein said formulation contains from about 0.5 mg to about 200 mg of the serotonin agonist.

Claim 8. (currently amended): The formulation of claims 1-~~9~~, wherein the unit dose provides pain relief within less than about 15 minutes to about 3 hours, within less than about 15 minutes to about 24 hours, within less than about 15 minutes to about 2 hours, within less than about 15 minutes to about 30 minutes, and preferably within from less than 1 minute to about 2 hours after application of the unit dose to the affected area.

Claim 9. (currently amended): The formulation of claims 1-~~8~~, wherein the unit dose provides pain relief in at least 50 percent of a population of patients in a time period within about 2 hours after application of the unit dose to the affected region.

Claim 10. (currently amended): The formulation of claims 1-~~9~~, wherein the topical formulation is an aqueous based formulation.

Claim 11. (currently amended): The formulation of claims 1-~~10~~, wherein the formulation further comprises a permeation enhancer.

Claim 12. (currently amended): The formulation of claims 1-~~11~~, wherein the topical formulation is selected from the group consisting of a liquid, a semisolid, a solid and mixtures thereof.

Claim 13. (original): The formulation of claim 12, wherein the liquid is in the form of drops, tinctures, sprays, suspensions, lotions, emulsions, dispersions or mixtures thereof.

Claim 14. (original): The formulation of claim 12, wherein the semisolid is in the form of an ointment, cream, foam, paste, gel or mixtures thereof.

Claim 15. (original): The formulation of claim 12, wherein the solid is in the form of a powder, granulates, pellets, microcapsules or mixtures thereof.

Claim 16. (currently amended): The formulation of claims 1-~~15~~, wherein the unit dose of active agent(s) provides a subtherapeutic plasma level if orally administered, but is therapeutically effective when administered topically at the affected region.

Claim 17. (currently amended): The formulation of claims 1-~~16~~, wherein the unit dose provides pain relief in at least 70%, preferably at least 80%, and most preferably at least 90% of a population of patients.

Claim 18. (currently amended): The formulation of claims 1-~~3, 5 and 11-20~~, wherein the ergot alkaloid is selected from the group consisting of bromocriptine, ergocristinė, ergocristinine, ergotamine, ergotaminine, ergocryptine, ergocryptinine, ergocornine, ergocorninine, ergosine, ergosinine, ergonovine, ergometrinine, dihydroergotamine, lisuride, d-lysergic acid, d-isolysergic acid, lysergol, lergotrile, metergoline, methysergide, methylergonovine, pharmaceutically acceptable salts thereof, active metabolites thereof, prodrugs thereof and mixtures thereof.

Claim 19. (original): The formulation of claim 18, wherein the ergot alkaloid is selected from the group consisting of dihydroergotamine base, dihydroergotamine mesylate, and mixtures thereof.

Claim 20. (currently amended): The formulation of claims 18-~~19~~, wherein the therapeutically effective amount of ergot alkaloid ranges from about 0.1 mg to about 10 mg, preferably from about 0.5mg to 6mg.

Claim 21. (currently amended): The formulation of claims 1~~-2 and 4-20~~, wherein the skeletal muscle relaxant is selected from the group consisting of afloqulone, baclofen, botulin toxins, carisoprodol, chlormezanone, chlorphenesin carbamate, chlorzoxasozone, cyclobenzaprine, clonazepam, dantrolene, diazepam, eperisone, idrocilamide, inaperisone, mephenesin, mephenoxalone, methocarbamol, metaxalone, mivacurium chloride, orphenadrine, phenprobamate, pridinol mesylate, quinine, tetrazepam, thiocolchicoside, tizanidine, tolperisone, pharmaceutically acceptable salts thereof, active metabolites thereof, prodrugs thereof and mixtures thereof.

Claim 22. (original): The formulation of claim 21, wherein the muscle relaxant is tizanidine hydrochloride.

Claim 23. (original): The formulation of claim 22, wherein the unit dose comprises from about 0.4 mg to 8 mg, preferably from about 0.2 mg to about 4 mg of tizanidine hydrochloride.

Claim 24. (original): The formulation of claim 21, wherein the muscle relaxant is cyclobenzaprine.

Claim 25. (currently amended): The formulation of claims 2~~-23~~, wherein the serotonin agonist is selected from the group consisting of sumatriptan, naratriptan, eletriptan, rizatriptan, zolmitriptan, almotriptan, frovatriptan, pharmaceutically acceptable salts thereof, active metabolites thereof, prodrugs thereof and mixtures thereof.

Claim 26. (original): The formulation of claim 25, wherein the serotonin agonist is sumatriptan.

Claim 27. (currently amended): The formulation of claims 2~~-26~~, wherein the unit dose comprises from about 0.5 mg to about 200 mg sumatriptan, from about 5 mg to about 200 mg sumatriptan, preferably from about 5 mg to 100 mg sumatriptan.

Claim 28. (currently amended): The formulation of claims 2-~~26~~, wherein the unit dose comprises from about 5 mg to 50 mg sumatriptan, preferably from about 5 mg to 25 mg sumatriptan.

Claim 29. (currently amended): The formulation of claims 1-~~28~~, further comprising one or more additional active agents.

Claim 30. (currently amended): The formulation of claims 1-~~29~~, further comprising one or more ingredients selected from the group consisting of ethoxydiglycol, water, glycerine, C_{12-15}alkyl benzoate, glyceryl stearate, dimethicone, cetearyl alcohol, cetearyl glucoside, polyacrylamide, cetyl alcohol, magnesium aluminum silicate, xanthan gum, aloe vera (aloe barbadensis), tocopheryl acetate (vitamin E acetate), prunus amygadalus amara (bitter almond) kernel oil, vitis vinifera (grape) seed extract, triticum vulgare (wheat) germ oil, retinyl palmitate (vitamin A palmitate), ascorbyl palmitate (vitamin C palmitate), pro-lipo multi-emulsion liposomic system, tetrasodium EDTA, phenoxyethanol, and sodium hydroxymethylglycinate.

Claim 31. (original): A metered dose device comprising:

a) multiple unit doses of a topical formulation, wherein each unit dose comprises a therapeutically effective amount of an active agent(s) incorporated into a pharmaceutically acceptable excipient for topical administration onto the skin of a human patient, the therapeutically effective amount of active agent(s) being selected from the group consisting of:

i) an ergot alkaloid;

ii) a skeletal muscle relaxant; or

iii) a combination of an ergot alkaloid and a skeletal muscle relaxant; and

b) an actuator capable of being actuated to dispense single unit doses from the device;

each unit dose providing the active agent(s) in a form which is immediately absorbable when the unit dose is applied onto human skin, the unit dose providing a therapeutic effect within about 2 hours after topical administration to the patient.

Claim 32. (original): The metered dose device of claim 31, wherein the formulation further comprises a therapeutically effective amount of a serotonin agonist.

Claim 33. (currently amended): The metered dose device of claims 31 ~~and 32~~, wherein the therapeutically effective amount of active agent is an ergot alkaloid.

Claim 34. (currently amended): The metered dose device of claims 31 ~~and 32~~, wherein the therapeutically effective amount of active agent is a skeletal muscle relaxant.

Claim 35. (currently amended): The metered dose device of claims 31 ~~and 32~~, wherein the therapeutically effective amounts of active agents are an ergot alkaloid and a skeletal muscle relaxant.

Claim 36. (currently amended): The metered dose device of claims 31~~-35~~, further comprising an actuator capable of being actuated to dispense single unit doses from the device.

Claim 37. (currently amended): The metered dose device of claims 31~~-36~~, wherein the metered dose device is a syringe without a needle.

Claim 38. (original): A method of treating migraines, cluster headaches, muscle sprains, muscle spasms, spasticity, tension headaches and tension related migraines with a topical formulation comprising applying a unit dose of a therapeutically effective amount of an active agent(s) incorporated into a pharmaceutically acceptable excipient onto the skin of a human patient, the unit dose comprising an active agent(s) being selected from the group consisting of:

i) an ergot alkaloid;

ii) a skeletal muscle relaxant; or

iii) a combination of an ergot alkaloid and a skeletal muscle relaxant;

the unit dose providing a therapeutic effect within about 2 hours after topical administration to the human patient.

Claim 39. (original): The method of claim 38, wherein the formulation further comprises a therapeutically effective amount of a serotonin agonist.

Claim 40. (currently amended): The method of claims 38-~~39~~, wherein the therapeutically effective amount of active agent is an ergot alkaloid.

Claim 41. (currently amended): The method of claims 38-~~39~~, wherein the therapeutically effective amount of active agent is a skeletal muscle relaxant.

Claim 42. (currently amended): The method of claims 38-~~39~~, wherein the therapeutically effective amounts of active agents are an ergot alkaloid and a skeletal muscle relaxant.

Claim 43. (currently amended): The method of claims 38-~~42~~, wherein the formulation provides relief from a condition selected from the group consisting of migraines, cluster headaches, muscle sprains, muscle spasms, spasticity, tension headaches and tension related migraines.

Claim 44. (original): The method of claim 43, wherein the spasticity results from complication suffered in a stroke.